Remarks

I. SECTION 112, FIRST PARAGRAPH

Claims 9-12 stand rejected under section 112. first paragraph as failing to comply with the written description requirement. The basis for the rejection is that the claims are drawn to a method for inducing anti-Mtb immune responses by administering one or more of the specified peptides and the specification "does not provide any data that any of the peptides were actually administered *in vivo* or that there is any *in vivo* induction of anti-Mtb responses." Office Action page 3, lines 12-14. The rejection is traversed because compliance with the written description does not demand that *in vivo* data be provided for these method claims.

The written description requirement of section 112, first paragraph states that the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains...to make and use the same.... The function of the written description requirement is to "ensure that the inventor had possession as of the filing date of the application relied on, of the specific subject matter later claimed by him. In re Wertham, 541 F.2d 257, 262 (CCPA 1976). In Regents of the University of California v. Eli Lilly & Co., the Court of Appeals for the Federal Circuit concluded that a claim to a microorganism containing a human insulin cDNA was not adequately described by a statement that the invention included human insulin cDNA. Id. at 1567, 43 USPQ2d at 1405. The recitation of the term human insulin cDNA conveyed no distinguishing information about the identity of the claimed DNA sequence, such as its relevant structural or physical characteristics. Id. The court stated that an adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention," and that none of those descriptions appeared in that patent. Id. at 1566, 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606).

The specific subject matter claimed is a method for inducing an anti-Mtb immune response by administering to a mammal at least one of the specified peptides. The specification discloses:

> "*Peptides as Antigens*. The Mtb vaccine candidate peptides are useful as antigens for raising anti-Mtb immune responses, such as T cell responses (cytotoxic T cells or T helper cells). An "antigen" is a molecule or a portion of a molecule capable of stimulating an immune response, which is additionally capable of inducing an animal or human to produce antibody capable of binding to an epitope of the antigen. An "epitope" is that portion of any molecule capable of being recognized by and bound by an MHC molecule and recognized by a T cell or bound by an antibody. An antigen can have one or more than one epitope. The specific reaction indicates that the antifwen will react, in a highly selective manner, with

its corresponding MHC and T cell, or antibody and not with the nultitude of other antibodies which can be evoked by other antigens. Page 5, line 24 – page 6, line 2.

A peptide is "immunologically reactive" with an T cell or antibody when it binds to an MHC and is recognized by a T cell or binds to an antibody due to recognition (or the precise fit) of a specific epitope contained within the peptide. Immunological reactivity can be determined by measuring T cell response in vitro or by antibody binding, more particularly by the kinetics of antibody binding, or by competition in binding using as competitors a known peptide containing an epitope against which the antibody T cell response is directed. The techniques for determining whether a peptide is immunologically reactive with a T cell or with an antibody are known in the art. The peptides can be screened for efficacy by in vitro and in vivo assays. Such assays employ immunization of an animal, e.g., a rabbit or a primate, with the peptide, and evaluation of titers antibody to Mtb or to synthetic etector peptides corresponding to variant Mtb sequences." Page 6, lines 3 - 13.

"*Treatment of Mtb infection.* The method for reducing the levels of Mtb involves exposing a human to a Mtb vaccine candidate peptides, actively inducing antibodies that react with Mtb, and impairing the multiplication of Mtb in vivo. This method is appropriate for an Mtb infected subject with a competent immune system, or an uninfected or recently infected subject. Page 9, lines 11 - 16.

"The amount of Mtb vaccine candidate peptide required to induce an immune response, preferably a protective response, or produce an exogenous effect in the patient without significant adverse side effects varies depending upon the pharmaceutical composition employed and the optional presence of an adjuvant. Generally, for the compositions containing Mtb vaccine candidate peptide, each dose will comprise between about 50 μg to about 1 mg of the Mtb vaccine candidate peptide immunogens/ml of a sterile solution. A more preferred dosage can be about 200 μg of Mtb vaccine candidate peptide immunogen. Other dosage ranges can also be contemplated by one of skill in the art." Page 10, lines 6 – 13.

The sequence of each of the peptides specified in the pending claims is disclosed in Figure 4. For example, Figure 4 discloses that the sequence of the peptide defined in the claims as SEQ ID NO: 47 is NFLLPDAQSIQAAAGFASK. The Figure discloses the sequence for each of the peptide defined in the claims.

In addition, in Example 2, the specification discloses that 28 additional peptides predicted by the EpiMer algorithm were tested in humans to determine if they would induce a proliferative response. All 28 were found to induce a proliferative response in at least one Mtb-immune individual (persons previously exposed to Mtb). In the control group of Mtb-naïve individuals (persons not previously exposed to Mtb), these peptides induced a proliferative response in more than half the Mtb-naïve individuals tested. Page 28, lines 8-15. This data demonstrates that the peptides predicted by the EpiMer algorithm to

induce proliferative responses actually do induce proliferative responses in Mtb immune and naïve individuals.

In view of the data disclosed for the 28 peptides disclosed but not claimed, one of ordinary skill in the art would readily conclude that similar responses would be observed in individuals administered the claimed peptides, which peptides were also chosen by the EpiMer algorithm.

The written description requirement is met by this disclosure. The sequences of the claimed peptides chosen by the EpiMer algorithm are precisely and specifically disclosed in the specification. Also disclosed is that other peptides chosen by the EpiMer algorithm elicited the expected response when administered in humans. The skilled artisan would expect therefore that the claimed peptides would likewise elicit the same response as the 28 tested peptides. Reconsideration and withdrawal of the rejection is respectfully requested.

II. SECTION 102(e)

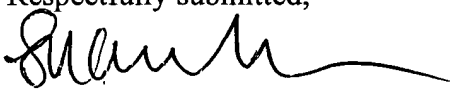
Claims 9-12 stand rejected under section 102 (e) as anticipated by the Gennaro US Patent, No. 6,087,163 ("Gennaro") because the sequence of one of the antigenic peptides claimed by applicant is part of a full amino acid sequence disclosed in Gennaro. This rejection is traversed.

Gennaro discloses the entire amino acid sequence for the MPT63 and MPT28 proteins of Mtb, and their corresponding nucleotide sequences. Gennaro purports to include as an embodiment of the invention antigenic polypeptides derived from the amino acid sequences disclosed, but fails to disclose any such polypeptides. Moreover, Gennaro fails to disclose any methodology that one skilled in the art could use to identify any antigenic epitopes within the full sequence, let alone the antigenic polypeptide claimed by applicant. Thus, Gennaro is not an enabling disclosure of the claimed invention. Regents of the Univerisity of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997); Chiron Corp. v. Genentech, 363 F.3d 1247 (Fed. Cir. 2004). Because it does not disclose or enable the peptides claimed, it cannot anticipate claims 9-12. Reconsideration and withdrawal of the rejection are respectfully requested.

III. CONCLUSION

The written description requirement is met in this application because the specification precisely discloses the peptide sequences and the method of inducing the claimed response. The claims are not anticipated by Gennaro because none of the peptides claimed are disclosed or enabled by the Gennaro disclosure. Reconsideration and withdrawal of the rejections are respectfully requested.

Respectfully submitted,



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